

13.0 MISCARRIAGE

STATEMENT TO THE PUBLIC




The reviewers expressed their judgments using two distinct sets of guidelines to evaluate the evidence:

- ***Using the traditional guidelines of the International Agency for Research on Cancer (IARC), they considered EMFs as a “possible risk” for miscarriage, category 2B. (IARC itself only evaluates cancer and did not discuss miscarriage. The National Institutes for Environmental Health Sciences classified the evidence as “inadequate.”)***
- ***Using the Guidelines developed especially for the California EMF program, all of the reviewers were “close to the dividing line between believing or not believing” that high residential or occupational EMFs cause some degree of increased risk of miscarriage.***

There are several reasons for the differences between the DHS reviewers and those of NIEHS. First, the two large miscarriage studies by Lee et al. and Li et al. had not yet come out at the time of the NIEHS review. Second, the three DHS scientists thought there were reasons why animal and test tube experiments might have failed to pick up a mechanism or a health problem; hence, the absence of much support from such animal and test tube studies did not reduce their confidence much or lead them to strongly distrust epidemiological evidence from statistical studies in human populations. They therefore had more faith in the quality of the epidemiological studies in human populations and hence gave more credence to them. While rodent and chicken egg studies provide little or no support for EMF effects, some studies on early-model higher emitting video display terminals (VDTs) and two new epidemiology studies in humans suggest that EMFs might cause a substantial proportion of miscarriages. Miscarriages are common in any case (about 10 per 100 clinically diagnosed pregnancies) and the theoretical added risk for an EMF-exposed pregnant woman might be an additional 10 per 100 pregnancies according to these two studies. If truly causal this could clearly be of concern to individuals and regulators. However, the type of EMF exposures implicated by these two new epidemiological studies (short, very high exposures) probably come from being within a few inches of some appliances and unusual configurations of wiring in walls and grounded plumbing, and only rarely from power lines. Since the majority of us come into contact with non-obvious sources of these fields on a daily basis, it may not be possible to avoid the majority of such exposures in modern life, even if we avoided the obvious sources like appliances.

Seventy-five percent of the women in the studies had at least one of these brief high exposures during a given day. Even one exposure a day, if experienced regularly during pregnancy, seemed to increase the risk of miscarriage. Nonetheless, the majority of pregnant women with such exposures did NOT miscarry.

The EMF Program's policy analysis required each of the three DHS scientists to express in numbers their individual professional judgments that the added personal risk suggested by the epidemiological studies was “real.” They did this as a numerical “degree of certainty” on a scale of 0 to 100. The three scientists each came up with a graph that depicts their best judgments with a little “x” and the margin of uncertainty with a shaded bar. The differences in certainty between the three reviewers arises primarily from how sure they were that they could rule out study flaws or other explanatory agents and how much the evidence on one disease influenced certainty in the findings for other diseases.

CONDITION	REVIEWER	IARC CLASS	CERTAINTY PHRASE	DEGREE OF CERTAINTY FOR POLICY ANALYSIS THAT AN AGENT (EMFs) INCREASES DISEASE RISK TO SOME DEGREE
Spontaneous Abortion	1	2B	Close to dividing line	0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100 
	2	2B	Close to dividing line	
	3	2B	Close to dividing line	

13.1 THE PATTERN OF EPIDEMIOLOGICAL EVIDENCE

TABLE 13.1.1 VDT AND SPONTANEOUS ABORTION STUDIES

STUDY NAME, INFORMATION	DESCRIPTION	STUDY NUMBER	INDIVIDUAL ODDS RATIO, MEAN	LOWER CL	UPPER CL
(Ericson & Kallen, 1986a)	>20 hrs/week	1	1.20	0.90	1.70
(Ericson & Kallen, 1986b)	High	2	1.1	0.9	1.2
(McDonald, Cherry & Delorme, 1986)	30 hrs vs. none	3	1.1	0.9	1.4
(Goldhaber, Polen & Hiatt, 1988)	>20 hrs/week	4	1.8	1.2	2.8
(McDonald, 1988)	>15 hrs vs. none	5	1.23	1.1	1.4
(Bryant & Love, 1989)	>20 hrs/week	6	1.1	0.6	2
(Windham et al., 1990)	>=20 hrs/week	7	1.3	0.9	1.8
(Nielsen & Brandt, 1990)	21-30 hrs/week	8	1.12	0.76	1.65
(Roman et al., 1992)	>=21 hrs/week	9	0.9	0.5	1.6
(Lindbohm et al., 1992)	Measurement of VDT models	10	3.40	1.40	8.60
(Schnorr et al., 1991)	High model vs. low model, >=25 hrs	11	1.00	0.61	1.64

1 Figure 13.1.1 and Table 13.1.1 show the reported relative risks (RRs) of
2 spontaneous abortions (SAB) conveyed by VDT use from 11 studies. The first 9
3 studies assessed exposure as hours of use, the 11th study (Schnorr, 1991)
4 compared users of two different types of VDTs where one was incorrectly assumed
5 to emit higher low frequency fields than the other, and the 10th study (Lindbohm,
6 1992) actually assigned exposure based on the laboratory measurements of the
7 user's VDT model. Nine out of 11 VDT studies were above an RR of 1.0 ($p = 0.03$)
8 while 4 out of 11 were above an RR 1.2 ($p = 0.16$). Only 1 of the 11 studies had an
9 RR above 1.5. The pattern associated with VDT use and miscarriage is slightly
10 above the "no-effect" RR.

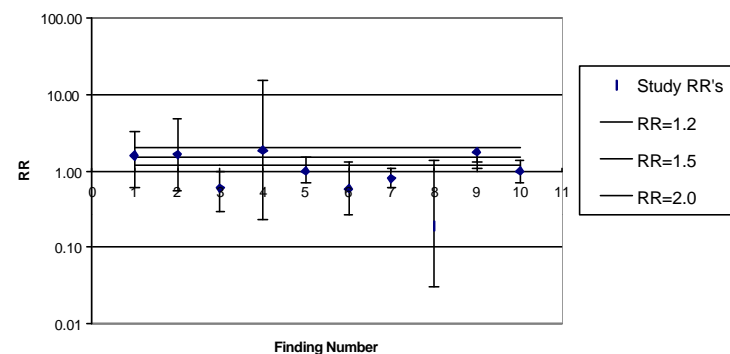


Figure 13.1.2 Electric Bed Heater and Home Cable Heat and Spontaneous Abortions Studies

TABLE 13.1.2 ELECTRIC BED HEATER AND HOME CABLE HEAT AND SPONTANEOUS ABORTION STUDIES

STUDY NUMBER	REFERENCE	FINDING NUMBER	EXPOSURE	EXPOSURE METRIC	INDIVIDUAL ODDS RATIO, MEAN	LOWER CL	UPPER CL
1	(Lee et al., 2000)	1	Electric blanket	High setting	1.60	0.60	3.30
2	(Belanger et al., 1998)	2	Electric blanket	High setting	1.65	0.56	4.86
1	(Lee et al., 2000)	3	Electric blanket	>= 6 hrs	0.60	0.30	1.00
2	(Belanger et al., 1998)	4	Electric blanket	>= 8 hrs	1.87	0.23	15.48
1	(Lee et al., 2000)	5	Water bed	High setting	1.00	0.70	1.50
2	(Belanger et al., 1998)	6	Waterbed	High setting	0.59	0.27	1.30
1	(Lee et al., 2000)	7	Waterbed	>= 8 hrs	0.80	0.60	1.10
2	(Belanger et al., 1998)	8	Waterbed	>= 8 hrs	0.19	0.03	1.40
3	(Wertheimer & Leeper, 1989)	9	Electric bed heater	Use	1.80	1.10	1.30
3	(Wertheimer & Leeper, 1986)	10	Home cable heat	Own	1.00	0.70	1.40

1 Figure 13.1.2 and Table 13.1.2 show the reported RR of SAB conveyed by home
 2 electric bed heaters (3 studies) and home electric cable heat (1 study). No matter

3 how one evaluates these electrical devices (e.g., grouped by setting; grouped by
 4 hours of use) the pattern is inconsistent.

Figure 13.1.2 SAB and Residential Spot Measurements and Wirecodes

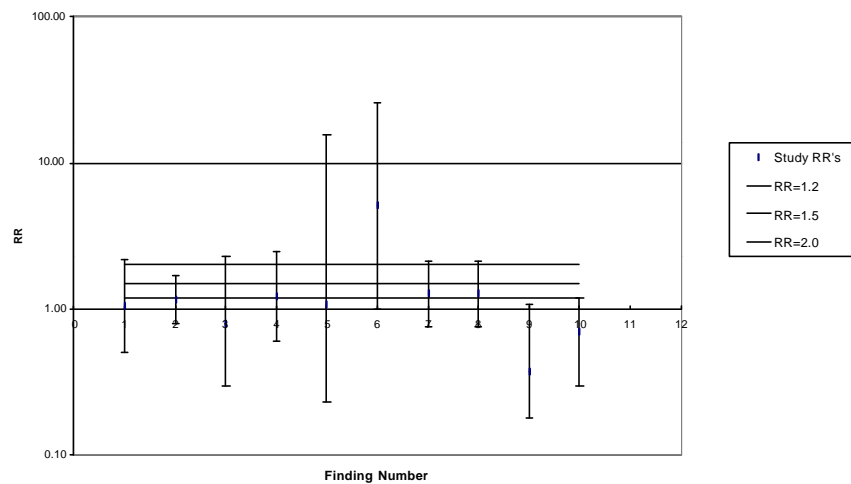


TABLE 13.1.3 SAB AND RESIDENTIAL SPOT MEASUREMENTS AND WIRE CODES

STUDY NUMBER	REFERENCE	FINDING NUMBER	EXPOSURE	EXPOSURE METRIC	INDIVIDUAL ODDS RATIO, MEAN	LOWER CL	UPPER CL
1	(Lee et al., 2000)	1	Inside Spots	≥ 2.0 mG	1.05	0.51	2.19
2	(Li et al., 2002)	2	Inside Spots	≥ 0.4 mG	1.15	0.79	1.68
3	(Savitz, 1994)	3	Inside Spots	≥ 2 mG	0.80	0.30	2.30
1	(Lee et al., 2000)	4	Front Door Spots	≥ 2.0 mG	1.22	0.60	2.49
2	(Li et al., 2002)	5	Front Door Spots	≥ 0.55 mG	1.07	0.23	15.48
4	(Juutilainen et al., 1993)	6	Front Door Spots	≥ 6.3 mG	5.09	1.00	26.00
1	(Lee et al., 2000)	7	Wire Code	Vh vs. Buried	1.27	0.76	2.14
2	(Li et al., 2002)	8	Wire Code	Vh vs. Buried	1.27	0.76	2.14
5	(Belanger et al., 1998)	9	Wire Code	Vh vs. Buried	0.37	0.18	1.09
3	(Savitz, 1994)	10	Wire Code	High vs. Low	0.70	0.30	1.18

1 Figure 13.1.3 and Table 13.1.3 show the reported RR of SAB conveyed by
2 residential magnetic field estimates (wire codes and home area measurements).
3 Overall, the pattern is inconsistent for these studies. Only one study found a
4 moderate RR for a high front door measure; this study assessed pre-clinical
5 spontaneous abortions while the others assessed clinical spontaneous abortions.

1 Figure 13.1.4 and Table 13.1.4 show the progression of RRs from lowest to highest
 2 quartile of the 24-hour personal maximum magnetic field exposures for the two
 3 studies (Lee, 2000b) and (Li 2000) that assessed the relationship of personal
 4 magnetic field measures and SAB. Lee and coworkers found a trend for
 5 progressively higher RRs with higher quartiles using measures below the 25th
 6 percentile value as the reference exposure while Li and coworkers found a plateau
 7 effect above the 25th percentile value.

8 How do these two studies relate to the many previous studies? The fact that wire
 9 code in these studies was NOT associated with maximum field (it is the rare power
 10 line, which delivers magnetic fields as high as 16 mG) makes it understandable that
 11 wire codes were also not clearly associated with miscarriage. The TWA was
 12 moderately correlated with maximum field, and the TWA was only weakly
 13 associated with miscarriage as with those found for some of the VDT and electric
 14 bed heater studies. Perhaps the predominance of RRs above 1.0 found for the VDT
 15 studies is reflecting an association with maximum fields and its EMF correlates, or
 16 some systematic bias.

Figure 13.1.3
Personal Maximum Dose Response
and Spontaneous Abortions

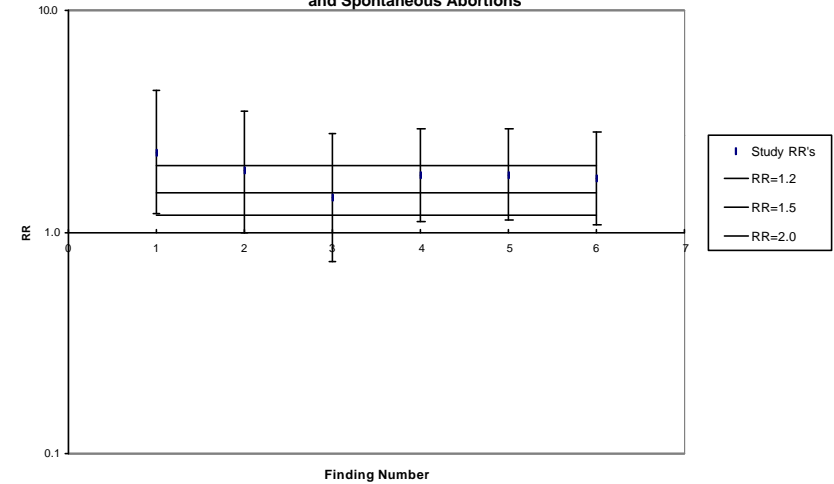


TABLE 13.1.4 PERSONAL MAXIMUM DOSE-RESPONSE AND SPONTANEOUS ABORTION

FINDING NUMBER	REFERENCE	FINDING NUMBER	EXPOSURE	EXPOSURE METRIC	INDIVIDUAL ODDS RATIO, MEAN	LOWER CL	UPPER CL
1	(Lee et al., 2000)	1	Personal Max	35.05 +	2.30	1.21	4.36
2	(Lee et al., 2000)	2	Personal Max	23.42 – < 35.05	1.90	1.00	3.50
3	(Lee et al., 2000)	3	Personal Max	14.31 – < 23.43	1.44	0.74	2.80
4	(Li et al., 2002)	4	Personal Max	49 +	1.81	1.12	2.95
5	(Li et al., 2002)	5	Personal Max	27 – < 49	1.83	1.14	2.96
6	(Li et al., 2002)	6	Personal Max	16 – < 27	1.76	1.08	2.86

TABLE 13.1.5 ADJUSTED ODDS RATIO (OR) OR RELATIVE RISK (RR) AND 95% CONFIDENCE INTERVAL (C.I.) OF THE ASSOCIATION BETWEEN TOTAL 24-HOUR PERSONAL MAGNETIC FIELD RATE OF CHANGE METRIC (RCM), MAXIMUM (MAX.) VALUE, AND TIME WEIGHTED-AVERAGE (TWA) OF SPONTANEOUS ABORTION BY QUALITIES FOR THE TWO PERSONAL MEASUREMENT STUDIES

Lee et al.					Li et. al.				
Max Value		Number	Percent	Adjusted OR * (95% C.I.)	Max Value		Number	Percent	Adjusted RR (95% C.I.)
35.05+	Case	39.0	29.8	2.30 (1.21-4.36)	49 +	Case	42	17.7	1.81 (1.12-2.95)
	Control	115.0	23.8			Control	196	82.4	
23.42 – < 35.05	Case	38.0	29.0	1.90 (1.00-3.51)	27-49	Case	48	19.8	1.83 (1.14-2.96)
	Control	115.0	23.8			Control	195	80.3	
14.31 – < 23.43	Case	33.0	25.2	1.44 (0.74-2.80)	16-27	Case	42	17.8	1.76 (1.08-2.86)
	Control	121.0	25.1			Control	194	82.2	
<14.31	Case	21.0	16.0	1.00 (Reference)	< 16	Case	27	10.7	1.00 (Reference)
	Control	132.0	23.8			Control	225	89.3	
RCM Value		Number	Percent	Adjusted OR * (95% C.I.)					
0.94+	Case	46.0	35.1	3.08 (1.59-5.95)					
	Control	109.0	22.5						
0.62 – < 0.94	Case	37.0	28.2	2.29 (1.19-4.40)					
	Control	118.0	24.4						
0.43 – < 0.62	Case	31.0	23.7	1.53 (0.768-3.05)					
	Control	126.0	26.0						
<0.43	Case	17.0	13.0	1.00 (Reference)					
	Control	131.0	23.8						
TWA		Number	Percent	Adjusted OR * (95% C.I.)					
1.28 +	Case	35.0	26.7	1.68 (0.87-3.23)					
	Control	123.0	25.5						
0.93 – < 1.28	Case	37.0	28.2	1.74 (0.92-3.30)					
	Control	114.0	23.6						
0.72 – < 0.93	Case	36.0	27.5	1.73 (0.91-3.26)					
	Control	122.0	25.3						
< 0.72	Case	23.0	17.6	1.00 (Reference)					
	Control	124.0	25.7						

* Adjusted for: maternal age, interview at gestation, coffee consumption at conception, income, race, and Kaiser facility

**Adjusted for: each of the variables listed above and the other personal metric

TABLE 13.1.6 SUMMARY OF SPONTANEOUS ABORTION STUDIES

STUDY NUMBER	REFERENCE	MEASURE TYPE	EXPOSURE	ODDS RATIO	LOWER CL	UPPER CL
1	(Lee et al., 2002)	TWA Personal	1.28 +	1.68	0.87	3.23
		TWA Personal	0.93 – < 1.28	1.74	0.92	3.30
		TWA Personal	0.72 – < 0.93	1.73	0.91	3.26
2	(Li et al., 2002)	TWA Personal	0.44	1.20	0.80	1.80
1	(Lee et al., 2002)	Max Value Personal	49 +	2.30	1.21	4.36
		Max Value Personal	21 – < 49	1.90	1.00	3.51
		Max Value Personal	16 – < 27	1.44	0.74	2.80
2	(Li et al., 2002)	Max Value Personal	35.05 +	1.81	1.12	2.95
		Max Value Personal	23.42 – < 35.05	1.83	1.14	2.96
		Max Value Personal	14.31 – < 23.43	1.76	1.08	2.86
1	(Lee et al., 2002)	RCM Personal	0.94 +	3.08	1.59	5.95
		RCM Personal	0.62 – < 0.94	2.29	1.19	4.40
		RCM Personal	0.42 – < 0.62	1.53	0.77	3.05
1	(Lee et al., 2002)	Inside Spots	<0.43	1.05	0.51	2.19
2	(Li et al., 2002)	Inside Spots	0.44	1.15	0.79	1.68
3	(Savitz, 1994)	Inside Spots	2.0	0.80	0.30	2.30
1	(Lee et al., 2002)	Front Door Spots	2.0	1.22	0.60	2.49
2	(Li et al., 2002)	Front Door Spots	0.55 mG	1.07	0.74	1.54
3	(Juutilainen et al., 1993)	Front Door Spots	6.3	5.09	1.00	26.00
1	(Lee et al., 2002)	Wire Code	VHCC	1.27	0.74	2.20
			OHCC	0.94	0.58	1.51
			OLCC	1.01	0.65	1.57

TABLE 13.1.6 SUMMARY OF SPONTANEOUS ABORTION STUDIES (CONT.)

STUDY NUMBER	REFERENCE	MEASURE TYPE	EXPOSURE	ODDS RATIO	LOWER CL	UPPER CL
2	(Li et al., 2002)	Wire code	VHCC	1.27	0.76	2.14
			OHCC	0.95	0.61	1.48
			OLCC	0.95	0.60	1.49
			VLCC	1.42	0.76	2.66
4	(Belanger et al., 1998)	Wire code	VHCC	0.37	0.18	1.09
3	(Savitz, 1994)	Wire code	High	0.70	0.30	1.18
3			Med	0.60	0.30	1.10
5	(Lee et al., 2000)	Electric blanket setting	Low	0.50	0.30	0.90
			Med	1.00	0.50	1.80
			High	1.60	0.60	3.30
4	(Belanger et al., 1998)	Electric blanket setting	None	1.00	1.00	1.00
			Daily low	1.34	0.47	3.86
			Daily high	1.65	0.56	4.86
5	(Lee et al., 2000)	Electric blanket hours	1	1.40	0.70	3.10
			2-5	0.70	0.30	2.00
			6+	0.60	0.30	1.00
4	(Belanger et al., 1998)	Electric blanket hours	None	1.00	1.00	1.00
			<8	1.45	0.63	3.25
			8	1.87	0.23	15.48
5	(Lee et al., 2000)	Waterbed setting	Low	1.00	0.60	1.80
			Med	6.20	0.40	0.90
			High	1.00	0.70	1.50

TABLE 13.1.6 SUMMARY OF SPONTANEOUS ABORTION STUDIES (CONT.)

STUDY NUMBER	REFERENCE	MEASURE TYPE	EXPOSURE	ODDS RATIO	LOWER CL	UPPER CL
4	(Belanger et al., 1998)	Waterbed setting	None	1.00	1.00	1.00
			Daily Low	0.70	0.27	1.77
			Daily High	0.59	0.27	1.30
5	(Lee et al., 2000)	Waterbed hours	<8	0.60	0.30	1.10
			8	0.80	0.60	1.10
4	(Belanger et al., 1998)	Waterbed hours	None	1.00	1.00	1.00
			<8	0.77	0.40	1.47
			8	0.19	0.03	1.40
6	(Lindbohm et al., 1992)	VDT, MF flux density	<0.4uT	1.00	1.00	1.00
			0.4-0.9	1.90	0.90	3.90
			>0.9	3.40	1.40	8.60
7	(Schnorr et al., 1991)	VDT Hours	None	1.00	1.00	1.00
			1-25	1.04	0.61	1.79
			25+	1.00	0.61	1.64
8	(Ericson & Kallen, 1986a)	VDT hours	>20 hrs/ week	1.20	0.90	1.70
9	(Ericson & Kallen, 1986b)	VDT hours	High	1.1	0.9	1.2
10	(McDonald et al., 1986)	VDT hours	30 hrs vs. none	1.1	0.9	1.4
11	(Goldhaber et al., 1988)	VDT hours	>20 hrs/ week	1.8	1.2	2.8
12	(McDonald, 1988)	VDT hours	>15 hrs vs none	1.23	1.1	1.4
13	(Bryant & Love, 1989)	VDT hours	>20 hrs/ week	1.1	0.6	2
14	(Windham et al., 1990)	VDT hours	20 hrs/week	1.3	0.9	1.8
15	(Nielsen & Brandt, 1990)	VDT hours	21-30 hrs/week	1.12	0.76	1.65
17	(Roman et al., 1992)	VDT hours	21 hrs/week	0.9	0.5	1.6

13.2 ARGUMENTS FOR AND AGAINST CAUSALITY

TABLE 13.2.1

CHANCE		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) Most of the VDT, wire code, and the electric bed heater study results are not statistically significant.	(F1) Although not all the positive VDT studies were significant, the number of studies above a relative risk of 1.0 (9 out of 11 VDT) showed a significant pattern ($p=0.03$). Given the different populations and indirect methods of assessing VDT use, not all studies are expected to be significant.	(C1) Chance alone is an unlikely explanation for the consistent positive associations for the VDT studies and the significant positive results of the two personal measurement studies where the studies had sufficient power to assess weak to moderate positive associations.
(A2) Many of these studies, especially the studies assessing personal measurements, have multiple comparisons and more than one way of dichotomizing the distributions of the exposures examined. This makes significant "p-values" less impressive.	(F2) For the two personal measurement studies (Lee, 2002), (Li, 2002), all comparisons were based on a <i>prior</i> hypothesis. The positive associations found were significant and consistent with each other. Furthermore, Lee et al. (Lee, 2000) reported Chi Square for trend p-values of less than 0.001 for the personal magnetic field and maximum and rate of change metric (RCM) values; this is unlikely to be explained by multiple comparisons of three personal metrics.	
(A3) The Li (Li et al., 2002) study used a post hoc cutpoint of 16 mG.	(F3) Examination of the cumulative distributions of the maximum field in the two personal measurement studies (Lee, 2002), (Li, 2002) and the RCM in the Lee (Lee, 2000) study does not suggest that results would be very sensitive to the choice of cutpoints. Li's 16 mG was the 25 th percentile for the cohort.	

TABLE 13.2.2

BIAS		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) The VDT studies may be the result of recall bias; women self-reported VDT use some time after the index pregnancy was complete. It is highly likely that women who had a spontaneous abortion were more likely to report VDT use than those who had live births, since the event of an abortion may trigger better recall of VDT use.	(F1) Recall bias is a definite possibility for most of these VDT studies. Non-differential misclassification bias may also play a major role in all these VDT studies under-estimating the true effects since VDT use is a very crude estimate of exposure during the first trimester.	(C1) If there is any bias in these studies, it is downward because of non-differential exposure misclassification, which also will distort dose response relationships. Recall bias is possible in the VDT studies.
(A2) Both of the personal measurement studies, (Lee, 2002) and (Li et al., 2002), had low participation response rates. This leaves more room for potential differential participation of cases and non-cases with regard to EMF exposure.	(F2) Studies like the two personal measurement studies require substantial subject cooperation and thus have high non-participation rates (Lee et al., 2002; Li et al., 2002). However it is unlikely that participants could know enough about EMF sources that produce brief high fields to differentially influence the decisions of cases and non-cases to enter Lee's case control study. It is even less likely that women in Li's (Li et al., 2002) prospective cohort study, who had not yet miscarried would differentially enter the study on the basis of their future miscarriage status and present brief high magnetic field exposure.	(C2) The personal measurement studies taken closer to the relevant time period give associations for TWA similar to those in the VDT studies and stronger associations for Max and RCM. Measuring one day out of a pregnancy will still produce exposure misclassification particularly for unstable measures like Max and RCM.
(A3) Half the miscarriages in Li's allegedly prospective study (Li et al., 2002) had already occurred when the magnetic field measurements were taken. These miscarriage cases COULD have decided to cooperate with the study based on their EMF exposure and thus biased the study. Indeed, when analysis was restricted to measurements taken before the miscarriage the association between miscarriage and EMF exposure was not statistically significant. That proves that bias had indeed occurred.	(F3) Li (Li et al., 2002) presents the associations between Maximum Field and miscarriage for early and late miscarriages for cases who had not yet miscarried and who had already miscarried at the time of measurement. The associations respectively are similar, an adjusted RR of 5.6 and 6.1 for <10 week gestation and a RR of 1.7 and 1.6 for gestations \geq 10 weeks gestation. The sample size of the before measurements was small; smaller numbers result in wider confidence intervals. But the data show similar associations regardless of whether the miscarriage occurred before or after the measurements. This does not suggest that substantial selection bias occurred in the Li study.	(C3) Each of the two studies assessed selection bias and the results support little or no selection bias.

BIAS		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A4) Lee's (Lee et al., 2002) study demonstrated some selection bias for wire code; cases with high current wires were more likely to enter the study than cases with lower wire code homes. This inflated the apparent association between wire code and miscarriage. This probably explains the apparent association between miscarriage and maximum fields or RCM.	(F4) There was a selection bias, which slightly inflated the wire code association with miscarriage, but not enough to be statistically significant. But wire code was not associated with maximum field or RCM so the slight selection bias on wire code could not explain the associations between miscarriage and maximum field or RCM. When one examines the associations between miscarriage and Max and RCM in Lee's prospective sub-study where selection bias could not have taken place, the associations are similar to those observed in the larger nested case control study. This does not support the hypothesis that selection bias occurred.	(C4) Recall bias is not a problem for the two personal measurement studies and the prospective electric bed heater studies, and the evaluation of selection bias in Lee (2002) and Li (2002) does not suggest much selection bias if any.
(A5) Lee (Lee et al., 2002) showed very low correlation between Max field and RCM at weeks 12 and 30. How could anything so unstable be validly measured on only one day? This must be due to selection bias.	(F5) In Li's (Li et al., 2002) study the association was really restricted to those measured on "typical" days. Lee's (Lee, 2002) poor correlations were with typical and atypical days taken together. If these measures are too unstable to predict disease, how can they be stable enough to predict participation in a study?	(C5) If maximum field and RCM on "typical" days are indeed unstable and poorly correlated, this could suggest that the associations observed are underestimates of the true effect.
	(F6) One should not use selection bias as a default explanation without evidence to support it.	

TABLE 13.2.3

CONFOUNDING		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) A weak to moderate confounder would easily "explain" the apparent positive associations found for the VDT and personal measurement studies since the effect measures in these studies are very close to one.	(F1) A hypothetical confounder could explain the weaker VDT associations but there is no specific evidence for this.	(C1) All studies with relative risks close to 1.00 are vulnerable to confounding regardless of the direction of the association. But this reasoning should not be used to routinely explain away positive associations close to the resolving power of the studies.
(A2) There are only a few known risk factors for spontaneous abortions making it difficult to control for the many unknown factors in the analysis.	(F2) Many of these studies, especially the personal measurement studies, adequately assessed known confounders and the positive associations remained.	(C2) For the studies where the exposure was objectively assessed, the positive associations were moderate and less likely to be explained by confounders.
	(F3) The personal measurement studies found moderate associations for some of their analyses; strong confounders would be needed to explain away these associations. No such confounders have been found even though strong confounders would more likely be known than not known.	(C3) Known risk factors did not explain away the personal magnetic field associations.

TABLE 13.2.4

STRENGTH OF ASSOCIATION		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) For the studies assessing sources believed to emit strong fields, such as the VDT and electric bed heaters, those studies showing positive associations found weak associations that are easily due to chance, bias, or confounding. Electric blankets should deliver maximum fields and high RCMs yet no dramatic risks have been documented.	(F1) Surrogate measures such as those used in the VDT and electric bed heater studies may suggest a risk that is not large enough to be easily detected by epidemiological studies due to random misclassification. Hence, they are expected to convey weaker relative risks than studies that measure the appropriate exposure metric directly. One of the electric bed heater studies (Lee et al., 2000) found that most of the women used an electric blanket on a low setting and exposures from low setting blankets were similar to background levels. Retinal doses from even high settings were low. VDTs may have emitted much weaker fields in the late 90s than they did in the 80s when most VDT studies were done, hence later studies would not be expected to show stronger associations.	(C1) Associations close to the resolution power of epidemiological associations (such as the VDT studies and electric bed heater studies) may reflect a true effect or bias or confounding. They should not be assumed to be due to bias or confounding without some evidence to support that hypothesis. See bias and confounding.
(A2) Also, evidence is lacking for a strong association between a woman's long-term residential exposure (assessed as wire codes) and spontaneous abortions.	(F2) Wire codes are a proxy for magnetic field exposure and may not capture the biological agent of the EMF mixture. The Lee (Lee et al., 2002) study found that the wire code was moderately associated with the magnetic field TWA but not associated with the maximum value or the rate of change metric, the measures found to be positively associated with spontaneous abortions.	(C2) The modest associations found for the personal measurement studies (Lee, 2002) and (Li, 2002) remained even after confounding and bias were taken into account. These two studies demonstrate consistent moderate associations between spontaneous abortions and maximum and RCM values with narrow confidence intervals.
(A3) Although the personal measurement studies (Lee, 2002), (Li, 2002) have modest associations, they are within the range of vulnerability to bias and confounding.	(F3) The strength of the consistent positive association found for the personal measures in the Li (Li 2002) and Lee (Lee 2000) studies, while moderate has narrow confidence limits. The association between Max and miscarriage was greater than 2.0 in early miscarriages.	(C3) The earlier studies based on questionnaires about VDT use and electrical bed heater use at medium/high settings gave results suggesting an effect near to the resolution power of the studies. This was compatible with the association seen in the personal measurement studies with TWA, the measure most comparable to the surrogates used in the VDT studies.

STRENGTH OF ASSOCIATION		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A4) Also, for the two personal measurement studies, a weaker non-significant association was found for the personal 24-hour magnetic field TWA. This is the metric which, when examined at the 90 th percentile, has been associated with some cancers and hence expected to be strongly associated with miscarriage.		(C4) The cancer studies have not evaluated the association with maximum field so it is hard to make comparisons.
(A5) Even the personal measurement studies have RR less than 2.00. "Real science" ignores such associations.		(C5) Some of the RR reported in Lee (2002) and Li (2002) are well above 2.00 but this is not a magic number in any case.

TABLE 13.2.5

CONSISTENCY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) To evaluate a causal association, only studies with statistically significant associations that are consistent across studies should be considered. The overall pattern of studies does not show a consistent statistically significant positive association.	(F1) Out of 11 major VDT studies assessing spontaneous abortions, 9 had relative risks slightly above one. A sign test reveals a low probability (.03) of this representing a chance pattern.	(C1) There is a greater tendency for relative risk estimates to be greater than 1.0 than less than 1.0, indicating a slight consistency across the VDT studies.
(A2) The very small, non-significant positive association pattern observed for the VDT studies should be interpreted with caution; the same bias occurring in multiple studies could produce an apparent but spurious consistency.	(F2) Although there are only two personal measurement studies, both show consistent results.	(C2) Both the personal measurement studies found relative risks above 1.0 for the magnetic field maximum levels.
(A3) Consistency can not be evaluated for the personal measurement studies since there are only two studies.		(C3) The bed heater studies are not consistent.

TABLE 13.2.6

HOMOGENEITY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) There appears to be a heterogeneous, overall pattern across studies. The results of the electric bed heater studies were inconsistent as well as the results of studies assessing spot or area measures.	(F1) The VDT studies, overall, reveal a weak positive association. The lack of homogeneity for the bed heater and area measurement studies most probably reflects the differences in assessing the exposure (as a self reported use obtained using different definitions of use or area measures obtained at different times) and in the differences in the study population.	(C1) The pattern of the VDT results is suggestive of a homogenous, positive association.
(A2) Homogeneity cannot be evaluated for the personal measurement studies since there were only two studies.	(F2) Both the two personal measurement studies (Li et al., 2002) and (Lee et al., 2002), are homogenous in that showed a statistically significant positive association for the personal magnetic field maximum exposure and a weaker for the personal magnetic field TWA exposure.	(C2) The homogenous findings of the personal measurement studies increase confidence in a causal association.
	(F3) If EMF acts in combination with other agents it might appear heterogeneous if those other agents were not always present equally in the various studies.	

TABLE 13.2.7

DOSE RESPONSE		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) The likelihood of a causal relation is strengthened if a dose-response effect (gradient) is found. No gradient is found for the VDT and electric bed heater studies.	(F1) The studies using surrogate estimates of exposure may not have adequately categorized the exposure into high to low exposure groups. The electric bed heater studies used hours of use and setting to categorize high to low exposure. The retrospective personal measurement study (Lee et al., 2002) indicated that this categorization probably did not distinguish the use of high exposure bed heaters from low exposure ones.	(C1) The evidence suggests an increase with increase in exposure for the studies where high to low exposure categorization was based on measurements, (e.g., between exposed and non-exposed).
(A2) Even for the prospective personal measurement study (Li et al., 2002) where the measurements were obtained at the biologically critical time, an orderly monotonic increase in risk was not found for an increase in exposure; this decreases the possibility of a causal association.	(F2) Most of the VDT studies only used hours worked as a means to categorize more exposure. In the one study where measured VDT exposure was used to categorize the devices into emitting high to low exposures, a clear dose response was observed (Lindbohm et al., 1992).	(C2) The Lee (Lee et al., 2002) study shows a progressive increase of risk with dose while the Li (Li et al., 2002) study does not. This may be due to the exposure misclassification for the two associated metrics.
	(F3) In the retrospective personal measurement study (Lee et al., 2002), a clear dose response was found for two personal 24-hour exposure metrics (maximum value and the RCM).	

TABLE 13.2.8

COHERENCE/VISIBILITY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) The personal measurement studies suggest risks of spontaneous abortion double when women experience the population's median for the maximum magnetic field. But the electric blanket studies do not show a doubling of risk at high settings or with prolonged use. It's not coherent.	(F1) The exposure delivered by electric blankets to different parts of the body varies. A lot to the skin, less to the uterus, and very little to the retina (Lee et al., 2000). It is not clear what, if any, target body site responds to magnetic fields to increase the risk of miscarriage. This could explain the apparent lack of coherence. The electric bed heater studies (Lee et al., 2000), (Belanger et al., 1998) both reported a significant and non-significant doubling of risk at high settings, respectively.	(C1) The lack of coherence with the electric blanket heater studies is acknowledged, but may have explanations as discussed.
(A2) The personal measurement studies suggest that 30 to 40 % of the background rate of miscarriages would be due to maximum magnetic field exposures. Why did we not notice this when electricity was introduced or subsequently as the use of appliances increased?	(F2) Miscarriages are not routinely monitored; as electricity use increased, a 30 to 40 % increase in rates could have been easily missed.	(C2) Increases in miscarriage rates could easily have been missed over time due a lack of a systematic reporting system.
(A3) The chance encounter with a maximum field would vary from day to day. It is puzzling that a "typical" day would be any more likely to capture this than an atypical day.	(F3) There are points of internal coherence in the personal measurement studies. Li (Li et al., 2002) shows a larger effect when analysis is restricted to "typical days" (e.g., when the measured exposure is more likely to reflect typical exposure), and a larger effect for women with a history of infertility or previous miscarriages. Both studies found a larger effect for earlier miscarriages.	(C3) The internal coherence of the studies is supportive of a causal association.
(A4) The personal maximum magnetic fields finding of the two personal measurement studies (Lee et al., 2002),(Li et al., 2002) are not coherent. One shows a monotonic dose response (Lee et al., 2002) while the other (Li et al., 2002) does not.		(C4) The fact that a stronger association with metrics that are less stable than the TWA is surprising. It is possible that a person who "typically" takes the electrical subway or usually enters some high exposure environment gets a range of maximum fields that they would not see on an atypical day where they did not do this.

COHERENCE/VISIBILITY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
		(C5) The lack of coherence in the shape of the dose response between the two measurement studies is acknowledged but may be due to the different exposure distributions of the two studies and hence different exposure reference levels. Li (Li et al., 2002) found higher exposures than Lee (Lee et al., 2002).

TABLE 13.2.9

EXPERIMENTAL EVIDENCE		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) There is no clear evidence from animal studies of an association of EMF exposure and spontaneous abortions. Chick bioassays are variable and have little regulatory weight.	(F1) A number of laboratory studies have reported alterations in the development of chick embryos exposed to EMFs. These mostly used pulsed fields similar to the "maximum peaks" associated with spontaneous abortions in the two personal measurement studies (Lee et al., 2002), (Li et al., 2002). Those mammalian studies that reported no associations all used steady high fields. The chick studies suggest biological effect at levels encountered in residential environments.	(C1) The evidence is not sufficiently extensive or clear. See Generic discussion.

TABLE 13.2.10

PLAUSIBILITY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) The melatonin hypothesis advanced by some lacks consistent experimental evidence that EMFs alter mammalian melatonin or that changes in melatonin increase the risk of spontaneous abortion.	(F1) Epidemiological studies by Burch (Burch, 1998; Burch, 1999) and Kaune (Kaune, Davis & Stevens, 1997) suggest a melatonin effect on humans, particularly with variable fields. Melatonin is linked to menstrual cycle hormones (Cagnacci & Volpe, 1996) and these relate to the menstrual cycle and conceivably to spontaneous abortions.	(C1) Biological mechanism arguments are still speculative. If links in mechanistic causal chain were all elucidated confidence would be boosted. Lack of a clear mechanistic understanding does not decrease the reviewers' confidence since clear mechanisms are not always available when epidemiological associations are first demonstrated.

TABLE 13.2.11

ANALOGY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
See "Generic Issues" Chapter.		

TABLE 13.2.12

TEMPORALITY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) The retrospective personal measurement study (Lee et al., 2002) measured exposure after the women in the cases had their miscarriages and while the controls were in their last gestation of pregnancy. Perhaps the cases reverted to a more active pre-pregnancy behavior far different from the current behavior of the controls due to their advanced pregnancy status. As a result, controls may experience lower EMF exposures than cases and than they would have experienced while not pregnant. This would explain the positive associations found.	(F1) The retrospective measurement study (Lee et al., 2002) also contained a pilot study based on measurements taken early in pregnancy and before any miscarriages. This study shows similar associations as the retrospective part of the study, albeit with wide confidence limits. This argues against a problem with temporality.	(C1) Tests of internal coherence in the two studies argue against a temporality problem.
(A2) Measurements were obtained after the miscarriage for 60% of the prospective measurement (Li et al., 2002) study. These cases could have changed behavior from their behavior while pregnant. This may bias the result upward as described in A1. The association was no longer significant from the measurements obtained prospectively.	(F2) The pattern of associations in the Li (Li et al., 2002) study is similar for the prospective and retrospective measurements. The same associations, which are statistically significant when the two types of measurements are combined, have wider confidence limits when the retrospective and prospective measurements are observed separately. (See discussion under Bias.)	
(A3) In the Li (Li et al., 2002) study, nauseated women destined to deliver a healthy baby may have stayed put and experienced a lower rate of change metric and fewer maximum fields than the women whose embryo as getting ready to be aborted.	(F3) In a letter to the editor Li, (Li & Neutra, 2002) provides data showing no association between nausea or vomiting and maximum field.	

TABLE 13.2.13

SPECIFICITY		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
See "Generic Issues" Chapter.		

TABLE 13.2.14

OTHER DISEASE ASSOCIATIONS		
AGAINST CAUSALITY	FOR CAUSALITY	COMMENT AND SUMMARY
(A1) The lack of associations with birth defects and other reproductive endpoints decreases the credibility of the positive results of the two personal measurement studies.	(F1) The quality and timing of exposure assessment for the other reproductive endpoints is not as good as the two personal measurement studies (Lee et al., 2002), (Li et al., 2002). Also, it is difficult to compare the spontaneous abortion results with the other reproductive endpoint findings since these endpoint are very heterogeneous and the methods of exposure assessment is very different across studies. They are much less frequent than miscarriage.	(C1) The lack of associations in the weak first generation studies of other reproductive endpoints does not carry much weight.
(A2) The positive findings found for the cancer study should not influence the credibility of the EMF and spontaneous abortion association since these conditions are not related to spontaneous abortions.	(F2) Given that it is not known that a specific mechanism applies to some endpoints associated with EMF and not to SAB, the existence of other associations should increase confidence to some degree.	(C2) The associations with other disease endpoints carry some weight.

TABLE 13.2.15

SUMMARY TABLE FOR MISCARRIAGE			
ATTRIBUTE OF THE EVIDENCE	HOW LIKELY IS THIS ATTRIBUTE OF THE EVIDENCE UNDER:		
	"NO-EFFECT" HYPOTHESIS	CAUSAL HYPOTHESIS	HOW MUCH AND IN WHAT DIRECTION DOES THIS ATTRIBUTE CHANGE CERTAINTY?
Chance not an easy explanation.	Less possible	More possible	Increase
Bias recall possible for VDT studies and random misclassification (bias toward the null), if any, in the personal measurement studies of Lee and Li.	Possible	More possible	No impact or slight increase
Confounding adequate for known risk factors, slight possibility for unknown risk factors.	Possible	More possible	No impact or slight increase
Combined effect of bias, confounding, and chance.	Possible	Possible	No impact
Strength of Association: (1) moderate, although not large enough to rule out unspecified bias or confounding.	Less possible	Possible	No impact or slight increase
Consistency found for VDT studies and two personal measurement studies.	Less possible	More possible	Increase
Homogeneity for personal measurement studies; heterogeneous with most residential studies.	Possible	More possible	Slight increase
Dose: response clear with one personal measurement study (other threshold effect) and VDT study that obtained a range of exposure.	Possible	More possible	Slight increase
Coherence/visibility: lack of surveillance system for SABs to adequately assess time trends and high exposure is rare so population impact would not be obvious.	Possible	Possible	No impact
Experimental Evidence: null animal studies.	More possible	Possible	No impact or slight decrease
Plausibility: melatonin hypothesis, not tested.	Possible	Possible	No impact
No analogy.	Possible	Possible	No impact
Specificity: see generic discussion.	Possible	Possible	No impact
Based mainly on two studies.	More possible	Less possible	Decrease

13.3 POSTERIOR (UPDATED) DEGREE OF CERTAINTY AND IARC CLASSIFICATION

13.3.1 STATEMENTS OF INDIVIDUAL REVIEWERS

1 Reviewer 1 (DelPizzo)

2 *Degree of Certainty:* The epidemiological evidence consists of two separate groups
3 of studies investigating what can reasonably be defined as two distinct research
4 hypotheses:

5 a) Is EMF exposure an epidemiologically detectable risk factor for spontaneous
6 abortion (SAB) (e.g., with a relative risk of at least 1.2)?

7 b) Is EMF exposure resulting from VDT work a risk factor for SAB?

8 The reason why the two hypotheses cannot be combined is that, compared to
9 residential and other occupational settings regarded as in the upper percentiles of
10 average exposure EMF, exposure from VDT work varies from very weak to
11 negligible, due both to the limited exposure time and to the historical trend toward
12 lower emission levels.

13 Therefore, for the purpose of evaluating the hypothesis, which is the subject of this
14 evaluation, the VDT studies can be regarded as a strengthening only type of
15 evidence. That is, it is permissible to pool VDT and residential studies to determine
16 the likelihood of the results under the null hypothesis (if EMF is not a risk factor,
17 both strong and weak exposures should yield results symmetrically distributed
18 around the null).

19 However, it is not permissible to use studies of exposure lower than that of interest
20 in our context to determine if this exposure imparts a risk above a given minimum.

21 With this premise, Reviewer 1 judges the pattern of results is unlikely under the
22 hypothesis of no effect. Additional confidence is derived by the analogy with the
23 childhood leukemia assessment and the replicated animal and *in vitro* studies at low
24 exposure levels. As noted elsewhere, their significance is not that of experimental
25 evidence directly supporting the hypothesis, but that of an argument against the
26 belief that EMF levels are too weak to affect.

27 Reviewer 1 has not relied on the Lee (Lee 2002) and Li (Li 2002) reports of
28 associations between maximum exposure and SAB because this metric was not the

29 reviewers' *a priori hypothesis*. However, these recent results confirm Reviewer 1's
30 evaluation and beg for further investigations.

31 In qualitative terms, this reviewer is "close to the dividing line between believing and
32 not believing" that VDTs and EMFs increase the risk of miscarriage to some degree.

33 For the purpose of decision analysis, Reviewer 1 believes that numerical values of
34 20 to 75 are defensible, with a median value of 56.

35 *IARC Classification:* 2B, possible human risk.

36 Reviewer 2 (Neutra)

37 *Degree of Certainty:* Over the last two decades there have been a series of VDT
38 studies with inadequate exposure assessments showing somewhat consistent but
39 not homogenous results, yet which suggested the possibility of an EMF effect just
40 above the resolution power of the studies. The two large studies by Lee (Lee et al.,
41 2002) and Li (Li et al., 2002) were based on 24-hour personal measurements taken
42 during one day of pregnancy. They do not show a clear association with the average
43 of instantaneous fields but both show associations with the maximum field
44 experienced during the day that are somewhat above the resolution power of the
45 studies. The similar associations seen in these two well-conducted studies are
46 deemed unlikely to be due to chance or confounding with selection bias a possibility
47 in the first study and a remote possibility in the second study. The null mammalian
48 reproductive studies based on steady 60 Hz fields may not be relevant, while the
49 controversial chick studies using pulsed fields may be relevant but did not affect this
50 reviewers confidence much. The very suggestive evidence from only two studies
51 combined with the very weak evidence from the lower quality previous studies of
52 VDTs increased this reviewer's degree of certainty well above the prior. This would
53 best be characterized as "close to the dividing line between believing and not
54 believing" with a median estimate of 51 and a range from 20 to 70.

55 *IARC Classification:* The lack of support from mammalian pathology and clear
56 mechanistic explanation, in the face of only two state-of-the-art epidemiological
57 studies and a series of weaker studies compatible with a weak association with
58 average magnetic fields would qualify this as an IARC 2B possible abortifacient
59 based on "limited epidemiological evidence."




1 **Reviewer 3 (Lee)**

2 For evaluating the human evidence, Reviewer 3's posterior is increased
3 considerably from her prior by the results of the two well-conducted personal
4 measurement studies based on the studies' strength of the relative risks, dose
5 response, and threshold effects, as well as the temporal relationship between
6 exposure and effect, the adequate assessment of confounding, the adequate
7 assessment of exposure, and the consistency of the study results. The pre-clinical
8 study assessing the association of area measurements and miscarriage (Juutilainen
9 et al., 1993) and the VDT studies, as a group, support the positive associations of
10 these two personal measurement studies. The pre-clinical study found a positive
11 association and the VDT studies, and overall show a slight consistent positive
12 association. The home electric heater studies reveal an inconsistent pattern and
13 hence do not contribute to the body of evidence for or against a causal association.

14 However, Reviewer 3's posterior is slightly decreased by the lack of animal
15 pathology evidence. Hence, the posterior degree of certainty for purposes of the
16 policy analysis falls within the "close to the dividing line between believing and not
17 believing" category with a median value of 59 and a range of 30 to 85.

18 *IARC Classification:* Although the human evidence is mainly based on two personal
19 measurement studies, these studies make it easy to rule out chance, bias, and
20 confounding. The other studies using surrogate exposure measures provide some
21 background support. Although a rational biological hypothesis and mechanism have
22 been proposed, there is no animal evidence to support the proposal. Hence, EMF
23 belongs to the lower end of Group 2B, "possible" risk.

13.3.2 SUMMARY OF THE THREE REVIEWER'S CLASSIFICATIONS

CONDITION	REVIE- WER	IARC CLASS	CERTAINTY PHRASE	DEGREE OF CERTAINTY FOR POLICY ANALYSIS THAT AN AGENT (EMFs) INCREASES DISEASE RISK TO SOME DEGREE
Spontaneous Abortion	1	2B	Close to dividing line	
	2	2B	Close to dividing line	
	3	2B	Close to dividing line	

13.4 QUESTIONS RELEVANT TO DOSE RESPONSE AND POLICY

TABLE 13.4.1

HOW CONFIDENT ARE THE REVIEWERS THAT SPECIFIC EXPOSURE METRIC OR ASPECT OTHER THAN 60 HZ TWA MAGNETIC FIELD IS ASSOCIATED WITH THIS DISEASE?	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) Li and Lee suggest that changes in fields and brief high fields may be important.	(I1) If true, would focus on avoiding brief high exposures.

TABLE 13.4.2

EVIDENCE FOR THRESHOLD OR PLATEAU	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) For the personal magnetic field maximum levels, the results from Li and coworkers (Li et al., 2002) suggests a plateau after 16 mG, while the maximum results from Lee and coworkers (Lee et al., 2002) suggests a dose response. (C2) Neither provides evidence for a lower threshold of effect.	(I1) Unclear at this time.

TABLE 13.4.3

EVIDENCE FOR BIOLOGICAL WINDOWS OF VULNERABILITY	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) Both Li (Li et al., 2002) and Lee (Lee et al., 2002) provide evidence of effects from daytime exposure. (C2) Nighttime exposures are lower but there is a suggestion of effects from these exposures too. (C3) There is some suggestion for more effect early in pregnancy.	(I1) No basis for difference between night and day recommendations.

TABLE 13.4.4

CONSISTENT INDUCTION PERIOD OR REQUIRED DURATION OF EXPOSURE	
COMMENT AND SUMMARY	IMPACT ON POLICY
No evidentiary base.	None.

TABLE 13.4.5

EMFs COMPARED TO OTHER RISK FACTORS FOR THIS DISEASE	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) Similar size to maternal age, race, and other known risk factors. (C2) Large population attributable risk if causal.	(I1) Relative size is irrelevant to policy, which is driven by absolute added risk and prevalence of exposure. May be relevant to risk communication.

TABLE 13.4.6

RELATIVE RISK COMPARED TO THAT WHICH WOULD GENERATE 1/1,000 OR 1/100,000 THEORETICAL LIFETIME RISK	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) The added risk in the exposed group, if true, could be far larger than these benchmarks.	(I1) Of regulatory concern, if true.

TABLE 13.4.7

EVIDENCE FOR RACIAL OR CLASS DIFFERENCES IN EXPOSURE OR VULNERABILITY	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) Earlier studies did not address this. Lee (Lee et al., 2002) and Li (Li et al., 2002) looked for effect modification by race and income in their logistic regression models and found no significant terms for this. However, both studies are based on populations that are members of the Kaiser Permanente Medical Program health plan and hence represent a working population, not the general pregnant population, with perhaps a wider range of variability on ethnicity and social class.	No impact.

TABLE 13.4.8

ROOM FOR IMPROVEMENT IN QUALITY OR SIZE IN BEST EXISTING STUDIES	
COMMENT AND SUMMARY	IMPACT ON POLICY
<p>(C1) The earlier VDT studies were mostly subject to recall bias and had crude assessment of exposure.</p> <p>(C2) The electric bed heater studies only used surrogate assessment of exposure that may not reflect a person's personal nighttime exposure.</p> <p>(C3) Both VDTs and electric bed heaters have been re-engineered to give off lower magnetic fields in the mid 90s.</p> <p>(C4) The personal measurement studies (Lee et al., 2002) and (Li et al., 2002) are relatively large, expensive state-of-the-art epidemiological studies. Larger prospective studies with measurements on multiple days of pregnancy, with sub-studies to identify source of maximum fields would be ideal but expensive and perhaps not feasible because they would require unprecedented subject cooperation.</p>	<p>(I1) Requires research funding, which is not currently likely.</p> <p>(I2) Requires policy on how many further studies (if any) are needed.</p>

TABLE 13.4.9

NEW STUDIES IN PIPELINE	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) Not aware of other studies in pipeline.	(I1) Risk management decisions for at least a decade will need to rely on what's available.

TABLE 13.4.10

HOW LIKELY IS IT THAT FURTHER STUDIES COULD RESOLVE CONTROVERSIES?	
COMMENT AND SUMMARY	IMPACT ON POLICY
(C1) Using chick bioassay to explore bioactive exposure conditions might be useful. (C2) Further analysis of two personal measurement studies (Lee et al., 2002), (Li et al., 2002) to better understand exposure conditions could be useful. (C3) Using insights from the above to guide mammalian bioassays and further epidemiology could be useful.	(I1) Research funding and direction.

13.5 CONCLUSIONS ON POLICY-RELEVANT SCIENTIFIC ISSUES

13.5.1 DOSE-RESPONSE ISSUES

1 There is a clear, orderly, monotonic increase in risk with increase in personal
 2 magnetic field maximum exposures in one personal measurement study (Lee et al.,
 3 2002), while a plateau effect was found for the other study (Li et al., 2002). In the
 4 one VDT study (Lindbohm et al., 1992) where the VDT models were categorized
 5 into high to low EMF sources by laboratory measurements of the models used, a
 6 clear dose response was observed. For both of the personal measurement studies,
 7 an increased risk was noted around the 25th percentile value. Hence, if true, about
 8 75% of pregnant women would experience an exposure associated with an
 9 increased risk of miscarriage. The exposure could account for a substantial
 10 proportion of the background rate of spontaneous abortion.

13.5.2

11 The added risk EMF poses on miscarriage, if real, is of regulatory concern as
 12 described above. The two personal measurement studies suggest that change in
 13 magnetic fields and brief high fields may be an important influence on miscarriage
 14 risk. This will require policy to direct funding for future studies to understand the
 15 nature of the exposure, to evaluate the sources of such fields, and to decide
 16 whether or not to pursue methods for mitigation.